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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/637,962	THOMPSON, LAWRENCE H.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2003* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-68,76-85 and 117-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-68,76-85 and 117-130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *09 January 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14,16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 09 January 2003 (Paper No. 13) has been entered in full.

The information disclosure statement filed (07 March 2003, Paper No. 14) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The amendment filed 13 March 2003 (Paper No. 15) has been entered.

Acharya *et al.*, Ref. #11 (12 March 2003, Paper No. 16) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the drawings as set forth at pages 2-3 of the previous Office Action (09 September 2002, Paper No. 12) is *withdrawn* in view of the amendment (09 January 2003, Paper No. 13).

The rejection of claim 66 under 35 USC 112, second paragraph as set forth at page 3 of the previous Office Action (09 September 2002, Paper No. 12) is *withdrawn* in view of the amendment (09 January 2003, Paper No. 13).

The rejection of claims 66-68 and 76 under 35 USC 102(b) as being anticipated by Powell, US Patent No. 5,688,679 as set forth at pages 3-4 of the previous Office Action (09 September 2002, Paper No. 12) is *withdrawn* in view of Applicant's arguments (09 January 2003, Paper No. 13).

The rejection of claims 77-85 under 35 USC 103(a) as being as being unpatentable over Powell, US Patent No. 5,688,679 in view of Strickland, US Patent No. 5,661,125 as set forth at pages 4-6 of the previous Office Action (09 September 2002, Paper No. 12) is *withdrawn* in view of Applicant's arguments (09 January 2003, Paper No. 13).

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66 and 117 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. *This is a new matter rejection.* The specification as originally filed does not provide support for the invention as now claimed:

(claim 66) "the recombinant erythropoietin being other than Epoetin Alfa or Beta" and "wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta did not provide a therapeutic benefit within a treatment period".

(claim 117) "the recombinant erythropoietin being other than Epoetin Alfa or Beta" and "wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta produced an adverse effect in the subject".

In addition there is not support for "For example, under the conditions of an exhypoxic polycythemic mice assay" (page 15 of the specification).

Applicant's amendment, filed 09 January 2003 (Paper No. 13) and 13 March 2003 (Paper No. 15), asserts that no new matter has been added. Sufficient direction for the written description for the above-mentioned "limitations" has not been provided, therefore, the exact wording or connotations of the instant claims are not readily apparent.

Furthermore, the recitation of "other than Epoetin Alfa or Beta" appears to be a negative limitation. Adding the expressed exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts. See Ex parte Grasselli, 231 USPQ 393 (BPAI 1983).

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not

clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 66-68, 76-85 and 117-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for treating an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells, wherein the recombinant erythropoietin is Epoetin Omega, wherein Epoetin Omega is selected to provide a therapeutic benefit within a treatment period and wherein said subject is adversely effected by treatment with a therapeutic amount of Epoetin Alfa or Beta, does not reasonably provide enablement for:

a method for treating or preventing an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells, the recombinant erythropoietin being other than Epoetin Alfa or Beta, wherein the amount of recombinant erythropoietin administered is selected to provide a therapeutic benefit within a treatment period, and

wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta did not provide a therapeutic benefit within a treatment period or

a method for treating or preventing an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells, the recombinant erythropoietin being other than Epoetin Alfa or Beta, wherein the amount of recombinant erythropoietin administered is selected to provide a therapeutic benefit within a treatment period, and wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta produced an adverse effect in the subject.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Only Examples 5 and 6 of the specification will be discussed because only these examples relate to the instant claims. The specification teaches a subject who was initially administered Epoetin Beta to treat chronic anemia. The subject's hemoglobin was normal after treatment with Epoetin Beta but suffered from adverse reactions such as swelling and itching of the lower legs. The subject experienced the same symptoms with Epoetin Alfa. The subject was administered Epoetin Omega. The subject's hemoglobin was normal without the adverse reactions that occurred with Epoetin Alfa or Beta (page 54, Example 5).

The specification teaches a subject who was initially administered Epoetin Omega to treat chronic anemia associated with renal failure. The subject's hemoglobin

was normal after treatment with Epoetin Omega. After a first washout period of several months the subject was administered Epoetin Alfa. The patient failed to respond. After a second washout period, the subject was treated again with Epoetin Omega. The subject responded with a steady rise in hemoglobin.

The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure. The specification fails to teach a method using any *recombinant erythropoietin being other than Epoetin Alfa or Beta* to treat an anemic condition. The specification specifically teaches the use of Epoetin Omega. The specification fails to disclose that any recombinant erythropoietin can be used in the claimed methods.

The specification fails to teach a method of *preventing* an anemic condition. Prevent means to completely stop a condition from occurring. "Prevention" is not a relative term, it is total. The specification teaches the *treatment* of an anemic condition.

The specification does not disclose that prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta did not provide a therapeutic benefit within a treatment period. Example 5 demonstrated that the subject's hemoglobin was normal after treatment with Epoetin Beta. Thus, the subject in Example 5 did have a therapeutic benefit.

The specification fails to disclose a subject who was treated with Epoetin Alfa or Beta, was unresponsive and then responsive after treatment with Epoetin Omega. The subject in Example 6 was *initially* treated with Epoetin Omega, then Epoetin Alfa and then with Epoetin Omega again. The specification states that patients were randomized

to receive either Epoetin Omega **or Epoetin Alfa** in a first phase for 16-20 weeks, followed by a wash out period where no drug was administered for a period until hemoglobin levels returned to pre test (anemic) conditions, at which time in a second phase, the patient received the other of Epoetin Omega or Epoetin Alfa, whichever was administered in the first phase, after a second wash out period, a third phase followed, where the subject was returned to a different or similar dose of the drug used in the first phase (specification, page 55).

The specification states that there is a need for treating subjects that are non-responsive or adversely effected by treatment with Epoetins Alfa or Beta. Thus the invention is drawn to a population of subjects that are non responsive to initial treatment with Epoetin Alfa and Beta but respond to Epoetin Omega. While, the specification discloses that there was a washout period after administration of Epoetin Omega (hemoglobin returned to initial level), it is not clear what other long term effects could be occurring with initial treatment of Epoetin Omega that may adversely affect the activity Epoetin Alfa. A comparison cannot be made because the specification never disclosed those subjects who were first treated with Epoetin Alfa, then with Epoetin Omega, then Epoetin Alfa.

Due to the large quantity of experimentation necessary to treat or prevent an anemic condition a subject comprising administering recombinant erythropoietin being other than Epoetin Alfa or Beta, wherein said subject is non-responsive to treatment with Epoetin Alfa or Beta, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex

nature of the invention and the breadth of the claims which fail to recite limitations regarding recombinant erythropoietin, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
June 13, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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